

peutic intervention and trial monitoring and outcome evaluation. Complicating this situation is inconsistencies in CFS case definition. The main objective is to provide a critical review of the similarities and differences between the varying approaches to CFS case definition. The conflicts and controversies that have emerged as a result of the differing definitional criterion for CFS are highlighted and the potential impact on future research is identified. A critical review of the most frequently used case definitions in CFS was conducted. There are currently five case definitions of CFS; however, the most prominent is the 1994 Centre for Disease Control and Prevention Case Definitions. However, *prima facie* comparative advantages of this definition are elusive and indeed, it has been widely criticized for its lack of specificity. Counterintuitively, there is little compelling evidence to support the efficacy of any of the case definitions have produced evidence to demonstrate their accuracy or precision at defining cases of CFS. A summary description of the symptom profile for each of the case definitions is provided. The inconsistencies that have emerged in CFS research as a consequence of differing approaches to case definition are contrasted and discussed. Clinical and research implications are highlighted.

PHP113

IQWIG AND HIQA, WHAT ARE THEY GOOD FOR? THE EVOLUTION OF THE HTA AGENCY: TIME FROM CREATION TO FIRST ASSESSMENT AND IMPACTFUL APPRAISAL

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OBJECTIVES: To evaluate the time spent from the creation or charter of an HTA agency to endpoints indicating their effectiveness, such as publication of assessments and evidence of the incorporation of assessment into meaningful appraisal influencing patient access to health technologies. **METHODS:** This study looks at the creation of HTA agencies (e.g. AHRQ, HIQA, IQWiG, PBAC, CADTH and NICE) and their evolution in terms of roles in assessment (advisory, coordinating, decision-making) and the relationship they have with appraisal. **RESULTS:** It has been demonstrated that the time it takes for an agency to generate assessments impacting patient access varies widely. For example, in Ireland, HIQA was chartered in May 2007, and entrusted with performing HTA assessments. In 2008 and 2009, HIQA has published one health technology assessment per year, both of which were received and in turn implemented by the Minister for Health and Children. In comparison, NICE in the UK was founded in 1999, but its appraisals were not supported by mandate until 2005. Meanwhile, HTAs driven by DAHTA@DIMDI in Germany are known to rarely play a role in pricing and reimbursement. **CONCLUSIONS:** The evolution of HTA bodies has varied from country to country. However, evolution in scope and impact may provide useful lessons for countries where HTA is receiving renewed emphasis or where appraisal is under consideration for implementation, especially as new agencies are created and existing agencies evolve.

PHP114

OPTIMIZING THE ORGANIZATION; MIGRATING HEALTH SERVICES RESEARCH OPERATIONS INTO THE COLLABORATIVE SCIENCE CENTER OF EXCELLENCE

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The execution and management of Health Services Research projects can be an onerous task. Often there is no centralized body of knowledge within an organization around process and requirements. This leads to long execution timelines, difficulties with vendors and ultimately reduced productivity. The Collaborative Science Center of Excellence (CSCoE) was established in 2008 at Bristol-Myers Squibb (BMS). This group manages the global operations of a wide variety of programs, a portion of which includes worldwide investigator sponsored research, non-clinical research, expanded access, and risk evaluation and mitigation programs. Beginning June 2009, operational management of the entire US Health Economics and Outcomes Research (HEOR) book of work was moved from the OR Scientists into the CSCoE. This included administration, contract execution, master service agreement negotiation, financial management, protocol writing, AMCP dossier updates, and invoice tracking and payment. Within the first year over 90 projects were migrated into the CSCoE. Benefits the Health Services Research group realized included: 1. A consolidated 2010 and planned 2011 book of work; 2. A reportable repository of project information; 3. HEOR protocol and AMCP dossier improvement through standardization of in-house scientific writing; 4. Expedited contract execution; 5. Innovative cost-sharing; 6. Tiered and batched review of contracts reduced corporate legal hours; 7. Rapid response to organizational queries. Centralized process management unlocked latent value by allowing OR Scientists to focus on value-added activities, increased organizational transparency and agility, and moved operations to a lower cost environment.

POSTER SESSION I:

DISEASE-SPECIFIC STUDIES

Cardiovascular Disorders – Clinical Outcomes Studies

PCV1

DOES ROUTE OF ADMINISTRATION FOR ESTROGEN HORMONE THERAPY IMPACT RISK OF VENOUS THROMBOEMBOLISM: ESTRADIOL TRANSDERMAL SYSTEM VERSUS ORAL ESTROGEN-ONLY HORMONE THERAPY

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OBJECTIVES: To evaluate the risk of developing venous thromboembolism (VTE) events associated with the use of estradiol transdermal system (ETS; Vivelle-Dot®) relative to oral estrogen-only hormone therapy (HT) agents. **METHODS:** A health

insurance claims analysis was conducted using the Thomson Reuters MarketScan database from January 2002 through October 2009. Patients ≥ 35 years old newly initiated on an ETS or oral estrogen-only HT with ≥ 2 dispensings were analyzed. VTE was defined as ≥ 1 diagnosis code for deep vein thrombosis or pulmonary embolism. As a secondary outcome we assessed incident VTE resulting in hospitalization. Cohorts of ETS and oral estrogen-only HT were matched 1:1 based on both exact factor and propensity score matching. Incidence rate ratio (IRR) was used to compare the rates of VTE between the matched cohorts. Remaining baseline imbalances from matching were included as covariates in multivariate adjustments. **RESULTS:** Among the matched ETS and oral estrogen-only HT users (27,018 subjects in each group), the mean (SD) ages of the cohorts were 48.9 (7.1) years; in each cohort 6,044 (22.4%) and 1,788 (6.6%) patients had a hysterectomy and an oophorectomy at baseline, respectively. The mean (median) drug exposure for the ETS and oral estrogen-only HT cohorts was 391 (264) and 401 (272) days, respectively. A total of 115 ETS users developed VTE compared to 164 subjects in the estrogen-only HT cohort (unadjusted IRR: 0.72; 95% CI: 0.57-0.91, $P=0.006$). After adjustments, ETS remained statistically significantly associated with a lower incidence (33% reduction; $P=0.0134$) of VTE. The incidence rate reduction for hospitalization-related VTE events among the ETS users was even more pronounced with the adjusted incidence being 62% lower for ETS users relative to oral estrogen-only HT users. **CONCLUSIONS:** Results of this large population-based study showed that patients receiving ETS had a significantly lower incidence of VTE compared to patients receiving oral estrogen-only HT.

PCV2

THE RISK OF CARDIOVASCULAR EVENTS ASSOCIATED WITH DIETARY CALCIUM AND VITAMIN D SUPPLEMENTS IN PATIENTS WITH OSTEOPOROSIS

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OBJECTIVES: Calcium and vitamin D supplements have been widely used and recommended for women to prevent or delay the onset of osteoporosis and the risk of bone fractures. Other benefits include the improvement of blood pressure and lipid levels and a lowering of body weight. In theory, the beneficial effects of calcium and vitamin D suggest improvements in cardiovascular health. Recent publications suggest the contrary and allude to increase serum calcium as a risk factor for adverse cardiovascular events. This study examines whether the exposure to these supplements are associated with cardiovascular events. **METHODS:** The study was based on California Medicaid (Medi-Cal) fee-for-service administrative claims data from January 1995 to December 2002. The study population consist of patients >50 years with recorded diagnoses of osteoporosis followed from diagnoses date to the end of eligibility. Patients were excluded for prior use of the supplements or diagnosis of cardiovascular events or drug induced osteoporosis. Propensity score matching based on age, gender, elixhauser comorbidities and eligibility data created case ($n=1594$) and control groups ($n=4782$). Chi-square analysis was conducted for comparison of the cardiovascular events defined as ICD9 codes for myocardial infarction and searchable terms of "cerebral infarction, hemorrhage, ischemia" for stroke. **RESULTS:** No statistically significant relationship was found between the study groups for stroke ($p=0.56$) and myocardial infarction ($p=0.54$). Components of stroke included cerebral artery occlusion ($p=0.94$), precerebral artery occlusion ($p=0.27$), intracerebral hemorrhage ($p=0.23$), and subarachnoid hemorrhage ($p=0.05$). The clinical benefits of the supplements were evident with subarachnoid hemorrhage with 0 recorded diagnoses in the case group compared to 12 recorded diagnosis in the control group; however statistical significance was not established. **CONCLUSIONS:** The use of calcium and vitamin D supplementation yielded no relationship to the risk of adverse cardiovascular events. Moreover, no broad cardio-protective effects can be concluded from the study.

PCV3

RISK OF HOSPITALIZATIONS FOR VENOUS THROMBOEMBOLISM IN ATYPICAL VERSUS TYPICAL ANTIPSYCHOTIC USERS IN A NATIONAL SAMPLE OF MEDICARE BENEFICIARIES: A CLAIMS DATA ANALYSIS

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OBJECTIVES: To examine the difference between typical and atypical antipsychotic drug use in the risk of hospitalization for venous thromboembolism (VTE) in an elderly Medicare population. **METHODS:** This is a retrospective cohort study using 5% national sample of 2006-2007 Medicare claims data. Medicare beneficiaries with continuous Part A, B, and D enrollment in 2006-2007 and who initiated atypical or typical antipsychotic drug therapy in July 2006-June 2007 were included. All study subjects were followed for a period of 180 days from the date of index prescription. Atypical and typical users were matched on propensity score, calculated using pre-index demographics, clinical comorbidities, and medication use. A conditional logistic regression model stratified on the propensity score-matched pair using the Greedy matching algorithm was used to compare the risk of hospitalization for VTE in new users of atypical and typical antipsychotic drugs. Sensitivity analysis in the unmatched cohort was performed using propensity score as a continuous, linear term in logistic regression. **RESULTS:** A total of 15,637 new users of atypical and 2,337 new users of typical antipsychotic drugs were identified. There were 472 (2.6%) individuals with a hospitalization for VTE during follow-up. 417 were atypical and 55 were typical antipsychotic users. A 1:1 propensity score match yielded 2,333 matched pairs (4,666 individuals). In the matched cohort, 55 typical and 64 atypical drug users were hospitalized for VTE in the follow up period. Compared to typical antipsychotic users, users of atypical antipsychotics were less likely to have